

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Narasin and Tylosin Phosphate

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Elanco Animal Health. The NADA provides for use of approved, single-ingredient narasin and tylosin phosphate Type A medicated articles to make two-way combination Type C medicated feeds used as an aid in the prevention of coccidiosis, for increased rate of weight gain, and improved feed efficiency in broiler chickens.

DATES: This rule is effective [*insert date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: Charles J. Andres, Center for Veterinary Medicine (HFV-128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-1600.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed NADA 141-170 that provides for use of MONTEBAN® (36, 45, 54, 72, or 90 grams per pound (g/lb) narasin activity) and TYLAN® (10 g/lb of tylosin phosphate) Type A medicated articles to make combination Type C medicated broiler chicken feeds. The combination Type C medicated feeds contain 54 to 72 g/ton narasin and 4 to 50 g/ton tylosin phosphate and are used for the prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*, increased rate of weight gain, and improved feed efficiency in broiler chickens. The NADA is approved as of September

20, 2000, and the regulations in §§ 558.363 and 558.625 (21 CFR 558.363 and 558.625) are amended to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(2) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

2. Section 558.363 is amended in paragraph (d)(1) by adding paragraph (xi) to read as follows:

(d)(1)

21
CFR
10/20/00

§ 558.363 Narasin.

* * * *

(d) * * *

(1) * * *

(xi) *Amount per ton.* Narasin, 54 to 72 grams, plus tylosin, 4 to 50 grams.

(A) *Indications for use.* As an aid in the prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*, for increased rate of weight gain, and improved feed efficiency.

(B) *Limitations.* For broiler chickens only. Feed continuously as sole ration. Do not allow adult turkeys, horses, or other equines access to formulations containing narasin. Ingestion of narasin by these species has been fatal. Narasin sodium and tylosin phosphate as provided by 000986 in § 510.600(c) of this chapter.

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3. Section 558.625 is amended by revising paragraph (f)(2) to read as follows:

§ 558.625 Tylosin.

* * * *

(f) * * *

(2) Tylosin may also be used in combination with:

(i) Hygromycin B as in § 558.274.

(ii) Melengestrol acetate alone or in combination with certain ionophores as in § 558.342.

(iii) Monensin as in § 558.355.

(iv) Narasin as in § 558.363.

(v) Pyrantel tartrate as in § 558.485.

Dated: 10/16/00
October 16, 2000

S F Sundlof

Stephen F. Sundlof,
Director,
Center for Veterinary Medicine.

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL

Jim Windsor

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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